DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 4, 2015

Cardiac Science Corporation
Kathleen Roberts
Regulatory Compliance Manager
N7 W22025 Johnson Dr
Waukesha, Wisconsin 53186

Re: K143714
Trade/Device Name: Powerheart G5 AED
Powerheart G5 Defibrillation Pads
Powerheart G5 Defibrillation Pads with CPR Device
Powerheart G5 Pediatric Defibrillation Pads
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III
Product Code: MKJ, LIX
Dated: April 28, 2015
Received: April 29, 2015

Dear Kathleen Roberts:

This letter corrects our substantially equivalent letter of May 4, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

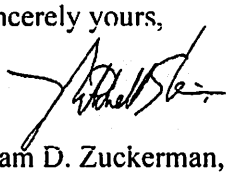
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Powerheart® G5 AED
Powerheart® G5 Defibrillation Pads
Powerheart® G5 Defibrillation Pads with CPR Device
Powerheart® G5 Pediatric Defibrillation Pads

Indications for Use:

The G5 Automated External Defibrillator (AED) is intended to be used by persons who have been trained in its operation. The user should be trained in basic life support or other physician-authorized emergency medical response.

An AED is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing or not breathing normally. Post-resuscitation, if the patient is breathing, the AED should be left attached to allow for acquisition and detection of the ECG rhythm. If a shockable ventricular tachyarrhythmia recurs, the device will charge automatically and advise the operator to deliver a shock, or for an automatic AED, automatically deliver a shock if needed.

When a patient is a child up to 8 years of age, or up to 25kg (55 lbs), the AED should be used with the Pediatric Defibrillation Pads. The therapy should not be delayed to determine the patient's exact age or weight.

The optional CPR Device offers CPR performance feedback to aid a trained rescuer by providing compression rate and depth performance feedback through audio prompting. The CPR Device is indicated for use on cardiac arrest patients 8 years of age or older, or who weigh more than 25 kg (55 lbs).

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

A. Submitter's name, address, telephone number, contact person, and date summary was prepared

Submitter	Cardiac Science Corporation N7 W22025 Johnson Drive Waukesha, WI 53186-1856
Contact Person	Kathleen Roberts Regulatory Compliance Manager Phone: (949) 797-3844 Fax: (949) 797-3801
Date Summary Prepared	May 4, 2015

B. Name of device, including trade name and classification name

Trade/Proprietary Name	Powerheart® G5 AED (Automated External Defibrillator) Powerheart® G5 Defibrillation Pads Powerheart® G5 Defibrillation Pads with CPR Device Powerheart® G5 Pediatric Defibrillation Pads
Classification Name	Automated External Defibrillator Cardiopulmonary Resuscitation Aid
Classification	Class III
Classification Number	21CFR 870.5310 21 CFR 870.5200
Product Code	MKJ, LIX

C. Identification of the predicate devices to which substantial equivalence is being claimed

Company	Cardiac Science Corporation
Device	Powerheart® AED G5
510(k) number	K122758
Date cleared	February 12, 2014
Company	ZOLL Medical Corporation
Device	Zoll AED Plus with CPR-D Padz
510(k) number	K120406
Date cleared	October 26, 2012

N7 W22025 Johnson Drive
Waukesha, WI 53186-1856
Tel: 262 953 3500
Fax: 262 953 3499
Toll Free: 800 426 0337

www.cardiacscience.com

D. Description of the device

The Powerheart® G5 AED is a portable, battery operated, self-testing defibrillator used to diagnose and treat life threatening ventricular arrhythmias in patients who are unresponsive and not breathing or not breathing normally. This is accomplished by monitoring the patient's ECG and delivering a defibrillation shock if necessary.

The AED is intended to be used by a person designated within a community, locale or building who is the first responder to a medical emergency. This typically includes ambulance, police or fire fighting personnel, emergency response team members, security personnel, and lay persons who have been trained in CPR and in the use of the AED.

The Powerheart® G5 AED guides the user through a rescue using voice or text prompts. Defibrillation pads are used to monitor and defibrillate patients. Defibrillation pads, meant for patients older than 8 years or heavier than 55 lb, are preconnected to the Powerheart G5 AED and placed in two locations on the patient during a rescue. Pediatric pads are connected to the AED when a pediatric patient is involved and meant for use on those patients 8 years or younger, or 55 lb or lighter.

The Powerheart® G5 CPR Device (CPRD), used in conjunction with the G5 AED, is a single use tool that provides CPR performance feedback to aid a CPR trained rescuer in the performance of CPR. The CPRD provides compression rate and depth audio feedback. CPR measurements are recorded for post-event review.

E. Intended use of the device

The G5 Automated External Defibrillator (AED) is intended to be used by persons who have been trained in its operation. The user should be trained in basic life support or other physician-authorized emergency medical response.

An AED is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing or not breathing normally. Post-resuscitation, if the patient is breathing, the AED should be left attached to allow for acquisition and detection of the ECG rhythm. If a shockable ventricular tachyarrhythmia recurs, the device will charge automatically and advise the operator to deliver a shock, or for an automatic AED, automatically deliver a shock if needed.

When a patient is a child up to 8 years of age, or up to 25kg (55 lbs), the AED should be used with the Pediatric Defibrillation Pads. The therapy should not be delayed to determine the patient's exact age or weight.

The optional CPR Device offers CPR performance feedback to aid a trained rescuer by providing compression rate and depth performance feedback through audio prompting. The CPR Device is indicated for use on cardiac arrest patients 8 years of age or older, or who weigh more than 25 kg (55 lbs).

F. Functional Tests

The Powerheart® G5 AED was subjected to performance hardware and software evaluations in accordance with industry standards. The G5 passed all software and hardware tests and was found to perform as intended.

Software

Software white box testing consisting of unit test, static analysis and code review was completed as well as unit and integration testing that was used to verify software requirements and functionality. Black box testing was conducted to ensure each device requirement was tested. Software analysis was performed using a static analysis tool.

Hardware

Hardware was qualified and functional testing was conducted to verify requirements and functionality. Design Failure Modes and Effects Assessments were completed for each PCBA contained within the AED and accessories.

Human Factors

Human factors testing was completed via execution of a simulated rescue. Each participant was able to apply the CPR Device, which was shown to not delay or distract from the correct use of the AED.

G. Technological Comparison with Predicate Devices

AED

The Powerheart® G5 AED, when used without the optional CPR Device, is identical to the G5 AED cleared in February 2014 via K122758. With the addition of a set of Dfibrillation Electrodes with CPRD, the AED will provide prompting to the user that is specific to the CPRD. Those prompts instruct the user to locate and open the CPRD pouch; to remove the CPRD and place on the patient's chest. If the AED recognizes CPR chest compressions that deviate from the AHA guidelines, the AED will provide corrective voice prompts.

Defibrillation Electrodes

The Powerheart® G5 Defibrillation electrodes that are the subject of this submission are unchanged from those cleared in February 2014 via K122758.

Defibrillation Electrodes with CPR Device

The Powerheart® G5 Defibrillation Electrodes with CPR Device is similar to the Zoll CPR-D padz in that each device measures the depth of chest compressions and guides the user to perform chest compressions, including when to begin CPR, when to provide breaths, correct number and rate and when to press/push harder or slow down/speed up compression rate.

The Powerheart® G5 Defibrillation Electrodes with CPR Device is different from the Zoll CPR-D padz in that the Zoll device includes a compression depth bar gauge that shows the depth of each compression. The method of guiding users to the correct rate of compressions is different. The Zoll CPR-D-padz sensor is attached directly to the electrode pads; the foam frame fixes the relative position of the electrodes and the CPR sensor. The G5 CPRD is packaged separately from the electrode pads. The CPRD and pads terminate in the same connector.

H. Conclusion

Cardiac Science has demonstrated through evaluation and testing of the Powerheart® G5 AED with optional CPR Device is substantially equivalent to the Powerheart® AED G5 and the Zoll CPR-D Padz. The AED is unchanged since the February 12, 2014 clearance on K122758, with the exception of prompting that is specific to the optional CPR Device. Based on the results of testing, it is concluded that the Powerheart® G5 AED with optional CPR Device does not raise any new questions regarding the safety or effectiveness as compared with the predicate devices.